IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

JUDITH CASTILLO	§	
	§	
Plaintiff,	§	
	§	
v.	§	Civil No.
	§	
BOSTON SCIENTIFIC CORPORATION,	§	
	§	
Defendant.	§	

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, JUDITH CASTILLO ("Plaintiff"), and complains of Defendant, BOSTON SCIENTIFIC CORPORATION ("Defendant") as follows:

PARTIES

1. This action seeks to recover damages for the injuries sustained by Plaintiff as the direct and proximate result of the wrongful conduct and negligence of the Defendant in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distributing, labeling, and selling of Solyx Single Incision Sling System manufactured by Defendant Boston Scientific, implanted in the Plaintiff.

2. Defendant Boston Scientific is a Delaware corporation with its corporate headquarters in Massachusetts. All acts and omissions of Boston Scientific as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership

3. At all times relevant herein, Defendant was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Solyx Single Incision

Sling System implanted in Plaintiff. At all times relevant hereto, and, upon information and belief, Defendant manufactured, marketed advertised, promoted and sold the Solyx Single Incision System worldwide.

4. Defendant had a legal duty to ensure the safety and effectiveness of their pelvic mesh products by conducting adequate and well-controlled studies on their products prior to marketing. Defendant deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients in the United States with inaccurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

JURISDICTION AND VENUE

5. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendant and the amount in controversy exceeds $75,000.

6. Defendant has significant contacts with the United States District Court for the Southern District of Texas such that it subject to the personal jurisdiction of the court in said district.

7. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in in the United States District Court for the Southern District of Texas. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

FACTUAL BACKGROUND

8. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse (POP") and stress urinary

incontinence ("SUI"). Manufacturers, including Defendant, began to modify the mesh used in hernia repair to be used a s products specifically intended to correct POP and SUI. Today, Defendant sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Solyx Single Sing System manufactured by Defendant (hereinafter referred to collectively as the "Mesh Products") is considered Class II medical devices.

9. The Mesh Products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

10. Moreover, these Mesh Products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving The Mesh Products. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh.

11. At various times, Defendant sought and obtained Food and Drug Administration ("FDA") clearance to market the Mesh Products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendant to prove the safety or efficacy of the Mesh Products

and, thus, a formal review of the safety and efficacy of the Mesh Products was never conducted with regard to the Products.

12. At all times relevant hereto, The Mesh Products were marketed to the medical community and directly to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment.

13. Upon information and belief, the Defendant has consistently underreported and withheld information about the propensity of the Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Mesh Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

14. Despite the chronic underreporting of adverse events associated with the Mesh Products, eventually enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

15. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" (emphasis in the original).

16. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA… Reports in the literature

associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

17. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologist Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> "There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh. Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable"

18. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

19. Plaintiff's injuries were reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion. 23. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

20. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

21. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologist Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted

that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh- related complications that are not experienced by patients who undergo traditional surgery without mesh."

22. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (emphasis in original).

23. The FDA White Paper further stated that "these products are associated with serious adverse events. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

24. In its White Paper, the FDA advises doctors to, inter alia, "Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

25. The FDA concludes the White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

26. Defendant knew or should have known about the Mesh Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

27. Defendant knew or should have known that the Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

28. Defendant had sole access to material facts concerning the defective nature of the Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Mesh Products.

29. The scientific evidence shows that the material from which the Mesh Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Mesh Products, including Plaintiff.

30. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

31. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an Issue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Mesh Products were unreasonably susceptible to degradation and fragmentation inside the body.

32. The Mesh Products were unreasonably susceptible to shrinkage and contraction inside the body.

33. The Mesh Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

34. At all times relevant hereto, the Mesh Products were marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

35. Defendant omitted the risks, dangers, defects, and disadvantages of the Mesh Products, and advertised, promoted, marketed, sold and distributed the Mesh Products as a safe medical device when Defendant knew or should have known that the Mesh Products were not safe for their intended purposes, and that the Mesh Products would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries.

36. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Mesh Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making these products defective under the law.

37. The specific nature of the Mesh Products' defects includes, but are not limited to, the following:

a. the use of polypropylene and collagen material in the Mesh Products and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Mesh Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Mesh Products, including, but not limited to, the propensity of the Mesh Products to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

38. The Mesh Products are also defective due to Defendant's failure to adequately warn or instruct Plaintiff and her healthcare providers of subjects including, but not limited to, the following:

a. the Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. the Mesh Products' propensities for degradation, fragmentation and/or creep;

c. the Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Mesh Products;

f. the risk of chronic infections resulting from the Mesh Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Mesh Products;

h. the risk of recurrent, intractable pelvic pain and other pain and other pain resulting from the Mesh Products;

i. the need for corrective or revision surgery to adjust or remove the Mesh Products;

j. the severity of complications that could arise as a result of implantation of the Mesh Products;

k. the hazards associated with the Mesh Products;

l. the Mesh Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. uses of the Mesh Products put the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

39. Defendant has underreported information about the propensity of the Mesh Products to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Mesh Products through various means and media.

40. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Mesh Products.

41. Defendant failed to design and establish a safe, effective procedure for removal of the Mesh Products, or to determine if a safe, effective procedure for removal of the Mesh Products exists.

42. Feasible and suitable alternatives to the Mesh Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Mesh Products.

43. The Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

44. Defendant provided incomplete and insufficient training and information to physicians regarding the use of the Mesh Products and the aftercare of patients implanted with the Mesh Products.

45. The Mesh Products implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendant's possession, and in the condition directed by and expected by Defendant.

46. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Mesh Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

47. In many cases, including Plaintiff's, the women have been forced to undergo extensive medical treatment, including, but not limited to operations to located and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine and the vagina, and operations to remove portions of the female genitalia.

48. The medical and scientific literature studying the effects of Defendant's mesh products, like that of the Mesh Products implanted in Plaintiff, has examined each of these injuries,

conditions, and complications, and has reported that they are causally related to the Mesh Products.

49. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

50. At all relevant times herein, Defendant continued to promote the Mesh Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

51. In doing so, Defendant failed to disclose to Plaintiff, Plaintiff's healthcare providers, and the medical community, the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Mesh Products.

52. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, Plaintiff's healthcare providers, and the medical community, on notice of the dangers and adverse effects caused by implantation of the Mesh Products.

53. The Mesh Products as designed, manufactured, distributed, sold and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant’s knowledge of lack of safety.

54. Defendant knew that the Mesh Products, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing.

55. The Mesh Products, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective as marketed at the time they left Defendant’s control.

56. On or about February 13, 2017, Plaintiff had the Mesh Product implanted at Edinburg Regional Medical Center in Edinburg, Texas.

57. Thereafter, Plaintiff began experiencing painful and serious complications, including but not limited to, infections; dyspareunia; abnormal discharge; constant, excruciating pain; urinary incontinence, and mesh erosion.

58. On or about November 5, 2019, Plaintiff underwent an operation at Pasteur Plaza Surgery Center in San Antonio, Texas, for excision of extruded transobturator tape vaginal sling and cystoscopy.

59. As a result of having the Mesh Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

CAUSES OF ACTION - COUNT I: NEGLIGENCE

60. Plaintiff hereby incorporates by reference all previous paragraphs and further states as follows:

61. Defendant had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Mesh Products.

62. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Mesh Products. Defendant breached their aforementioned duty by:

a. Failing to design the Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Mesh Products were implanted, including Plaintiff;

b. Failing to manufacture the Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Mesh Products were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Mesh Products was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Mesh Products so as to avoid an unreasonable risk of harm to women in whom the Mesh Products were implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Mesh Products;

63. The reasons that Defendant's negligence caused the Mesh Products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Mesh Products, including, but not limited to, the propensity of the Mesh Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Mesh Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

64. Defendant also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. the Mesh Products' propensities for degradation, fragmentation and/or creep;

c. the Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Mesh Products;

f. the risk of chronic infections resulting from the Mesh Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Mesh Products; the risk of recurrent, intractable pelvic pain and other pain resulting rom the Mesh Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Mesh Products;

i. the need for corrective or revision surgery to adjust or remove the Mesh Products;

j. the severity of complications that could arise as a result of implantation of the Mesh Products;

k. the hazards associated with the Mesh Products;

l. the Mesh Products defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products makes future surgical repair more difficult tan feasible available alternatives;

p. use of the Mesh Products puts the patient at a greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

65. As a direct and proximate result of Defendant's negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including multiple procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss,

including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

66. Plaintiff hereby incorporates by reference all previous paragraphs and further states as follows:

67. Plaintiff is an expected user or consumer of the Mesh Products.

68. The Mesh Products implanted in Plaintiff were conveyed in a condition not contemplated by reasonable persons among those considered expected users of consumers of the Mesh Products.

69. The Mesh Products implanted in Plaintiff were, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the Mesh Products at the time they were designed, manufactured, packaged, labeled, and/or sold.

70. The Mesh Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Mesh Products' design defects include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Mesh Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Mesh Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Mesh Products, including, but not limited to, the propensity of the Mesh Products to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Mesh Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Mesh Products to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Mesh Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Mesh Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

71. As a direct and proximate result of the Mesh Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including multiple procedures to correct her injuries and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including but not limited to obligations for medical services and expenses, and/or lost income and other damages.

72. Defendant is strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

73. Plaintiff hereby incorporates by reference all previous paragraphs and further states as follows:

74. The Mesh Products implanted in Plaintiff were not reasonable safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendant did not provide Plaintiff, Plaintiff's healthcare providers, or the medical community with sufficient or adequate warnings regarding among other subjects:

a. the Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. the Mesh Products' propensities for degradation, fragmentation, disintegration and/or creep;

c. the Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rated and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Mesh Products;

f. the risk of chronic infections resulting from the Mesh Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Mesh Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Mesh Products;

i. the need for corrective or revision surgery to adjust or remove the Mesh Products;

j. the severity of complications that could arise as a result of implantation of the Mesh Products;

k. the hazards associated with the Mesh Products;

l. the Mesh Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Mesh Products makes future surgical repair more difficult than feasible available alternatives;

p. the use of the Mesh Products puts the patient at a greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Mesh Products due to complications may involve multiple surgeries and may significantly impair the patients' quality of life; and

r. complete removal of the Mesh Products may not be possible and may not result in complete resolution of the complications, including pain.

75. Defendant, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

76. As a direct and proximate result of Defendant's failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Mesh Products.

77. As a direct and proximate result of the Mesh Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including multiple procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendant for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY

Dated May 12, 2020

Respectfully submitted,

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